No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* IN SUPPORT OF PETITION

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size enterprises that have annual revenues of under $25 million, and that count their patents among their most valuable business assets. Because modern biotechnological products commonly involve lengthy, resource and investment-intensive development periods, BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity. Accordingly, certainty regarding the types of transactions and what must be publicly disclosed about those transactions to qualify as invalidating activities under the on-sale bar of the America Invents Act (AIA) is of great importance to BIO.[1]

INTRODUCTORY STATEMENT

Small biotechnology companies are responsible for 70% of the global clinical pipeline and 84% of all drug

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1. BIO has no stake in the result of this appeal. Pursuant to Supreme Court Rule 37, all parties have consented to the filing of this brief. All parties were given notice of *Amicus'* intent to file this brief at least 10 days prior to its due date. No party other than the *amicus curiae*, its members, or its counsel, have authored the brief in whole or in part or made any monetary contribution intended to fund its preparation or submission.

development programs for rare diseases.[2] Imagine a typical example of one of the more than 2,000 small biotech companies in the United States. It was founded as a university spinoff to develop a treatment for one of the 7,000 rare diseases that affect one out of five Americans – on an idea that, at the time, was deemed too speculative by larger, established biopharmaceutical companies. The small company likely has fewer than 50 employees, occupies a leased facility, is burning upwards of $10 million per year, and has access to only enough venture capital to finance another fifteen months of research. The board is eager to put the business on more sustainable footing.

While initial research results are promising, everyone knows that it takes on average more than ten years of additional R&D before a new biotech therapy can be approved by the U.S. Food and Drug Administration.[3] But chances of that happening are slim: the likelihood that any of the company's new medicinal molecules will even advance to human testing is less than 1:1000. And the few compounds that do enter human testing empirically have a close to 90% failure rate.[4] What's more, the company has neither the funds (the out-of pocket costs of

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2. David Thomas and Chad Vessel, *Emerging Therapeutic Company Investment and Deal Trends, BIO Industry Analysis 2017*, available at: https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf

3. Jorge Mestre-Ferrandiz, Jon Sussex, Adrian Towne, *The R&D Cost of a New Medicine, Office Of Health Economics, London 2012*, available at https://www.ohe.org/system/files/private/publications/380%20-%20R%26D%20Cost%20NME%20Mestre-Ferrandiz%202012.pdf?download=1.

4. *Id.*

commercializing a biotech drug exceed $1.3 billion[5]) nor the expertise to conduct human clinical testing (this being the domain of larger biopharmaceutical companies). The company needs a partner to assume such cost and share the risk.

The company's leaders are eager to enter into discussions with potential partners and investors. Its research program includes valuable trade secrets, including samples and descriptions of several thousand new medicinal molecules. There is great concern about what can be disclosed in partnering meetings. Potential partners and investors want sufficient details about the company's research but are reluctant to sign confidentiality and non-disclosure agreements too soon.

Moreover, the small company does not yet know which of its thousands of experimental molecules will be the best candidates for human testing and should therefore be patented. Proactively filing hundreds of patent applications would be wasteful and unrealistic.[6] The company plans to file patent applications only for those molecules that are selected for human testing – but

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5. Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, Volume 47 May 2016, pp. 20-33.

6. Indiscriminate pre-emptive patent filing would tend to suppress pre-patent exploration of an invention to avoid potential "public" disclosure, thus stifling innovation and creating burdens on the patent system. *See* Christopher A. Cotropia, ***The Folly of Early Filing in Patent Law***, 61 Hastings L.J. 65 (2009); D. Karshtedt, ***The Riddle of Secret Public Use: A Response to Professor Lemley***, 93 Tex. L. Rev 159 (2015).

in order to get to that point, a partner is first needed. Fortunately, there are potential partners, but the ones willing to offer the most favorable terms are not interested in licensing but instead propose to acquire the program with a license of co-development rights back to the small company. Other potential partners are willing to make a preliminary investment but demand contingent assignment rights under which they would get to own the program for a predetermined payment if certain future milestones are met. The company's CEO and board are pleased: they deem such terms reasonable and a win-win for both sides.

Unfortunately, the company's lawyers are highly concerned because of a recent decision in the Court of Appeals for the Federal Circuit. *Helsinn v. Teva*, they explain, could well cause the proposed transaction to ruin future chances of patent protection for the company's molecules, and thereby destroy the value of the research program entirely. And the proposed deals would be deemed to place the company's secret molecules in the public domain, even though none of these molecules would actually be disclosed to anyone but the prospective business partner. Ultimately, the company decides to forego the proposed favorable deal and suspends its research program in the hope of finding other funding in the future. For the time being, research is not being done, and patients living with a rare disease will defer their hopes for a new treatment option.

Under the lower court's decision, no such problem or delay would be experienced if the inventors instead worked at a large pharmaceutical company that has the resources to develop its products without seeking partners. The

decision below, if allowed to stand, will impact innovative businesses of all sizes, but it will impact smaller companies more directly, and more harshly. Smaller companies are more dependent on partnering and external funding, and are more likely to have to report business transactions publicly, which would greatly increase the risk of unfairly triggering a patent-defeating event. The result below is especially harsh when a "sale" is deemed to have occurred in a clearly pre-commercial setting, long before it is even clear whether a biotech invention can receive FDA approval and actually be sold to the public, and where the transaction was undertaken to fund the development of the invention.

SUMMARY OF THE ARGUMENT

The Court should grant the writ for at least four reasons. First, it involves an important question of statutory construction suitable for resolution by this Court. The Court of Appeals declined to construe the 2011 amendments to 35 U.S.C. § 102(a), to address the effects of these amendments on its prior jurisprudence, and to explain how its ruling is grounded in the existing statute, resulting in a decision that is at once tentative and ambiguous.

Specifically, the Court of Appeals failed to explain what effect should be given to the amended language requiring that "the claimed invention was ... on sale, or otherwise available to the public." By avoiding discussion of this text, and by ruling that "if the existence of the sale is public, the details of the invention need not be publicly disclosed" (Cert. Pet. App. 43a), the Federal Circuit creates not only unmanageable uncertainty about the validity of

patents, but also an unnatural reading of section 102(a), which requires the claimed invention, not the sale, to be available to the public. The resulting business uncertainty is compounded by the lower court's unsuccessful effort at framing a narrow fact-bound ruling, which recites a haze of factors whose relevance to the on-sale bar would have been unclear even before the America Invents Act (AIA), Public Law 112-29-Sept. 16, 2011 amendments. Guidance from this Court would greatly assist the Court of Appeals in its task of construing the statute, thereby alleviating the uncertainty currently experienced by patent applicants and patent owners.

Second, the decision below is inconsistent with the United States Patent and Trademark Office's (USPTO) current patent examination practices. Since 2013, more than 300,000 patents have been examined and issued by the USPTO under an interpretation of the AIA that is now in doubt. Patent owners today are investing and building businesses in reliance on such patents. Yet, other than expressing disbelief that Congress might have wanted to modify its preexisting on-sale jurisprudence, the Court of Appeals offered no explanation why the USPTO's considered interpretation of the statute is unreasonable. In the interest of the integrity of the patent system this Court should intervene soon, or at least invite the views of the United States.

Third, in light of the AIA's territorial expansion of prior art, the decision below raises important questions about the effect of purely foreign conduct on the patentability of inventions made in this country. The Court of Appeals understood that its decision for the first time extends a patent-defeating effect to foreign conduct

having no nexus with, and being undetectable from, the United States, yet declined to discuss why Congress would have intended such an untenable result. This question is genuinely important for U.S. innovators who seek business partners abroad, and for foreign innovators seeking access to the U.S. market.

Fourth, no policy purpose would be served by letting the lower court opinion stand. To the contrary, the decision conflicts with Congress' stated policy goals, including substantive harmonization and creating more predictability for businesses and the public. By preserving a particularly problematic category of secret prior art in the amended 35 U.S.C. § 102, patents would be denied to deserving inventors who could not have known of invalidating business transactions, with no attendant benefits to the public. This would be compounded by expanding the scope of such secret prior art to the rest of the world. To the extent the Court of Appeals may have been concerned about secret commercial exploitation of later-patented inventions, it is worth noting that Congress, in the AIA amendments to 35 U.S.C. § 273, plainly endorsed the possibility that inventions can be secretly commercialized for profit and competitive advantage without creating prior art and without defeating the patentability of later-filed patent applications. The lower court's decision will be particularly detrimental to biotechnological innovation, where a majority of the new product development pipeline is held by small companies that depend on development and investment partnerships.

ARGUMENT

I. The Court Should Provide Guidance on the Statutory Construction of the 2011 Amendments to 35 U.S.C. § 102(a).

This Court should intervene to provide an answer to the dispositive question in this case: does a commercial transaction that does not inform the public about the claimed invention, nor make the invention available to the public, constitute prior art under the 2011 amendments to 35 U.S.C. § 102? There is no reason to let this urgent question fester for future resolution. The question is not narrowly fact-bound, and will not be presented any differently in the next case.

(a) The Court of Appeals' Atextual Interpretation of the AIA Sends Conflicting Messages.

The Court of Appeals declined to engage in any statutory construction of the 2011 amendments to 35 U.S.C. § 102, even though statutory construction was central to the district court holding and necessary to the disposition of the case. The amendments to 35 U.S.C. § 102 are significant, substantive, and generated more legislative commentary than any other section of the AIA. *See* J. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J., 435, at 449 (2012). In such a case, statutory construction is necessary.

However, while the Court of Appeals declined to say that the AIA modifies any aspect of its caselaw, it balked at saying that it does not. On the one hand, the panel's

analysis seems to contain an implicit acknowledgement that the AIA might incorporate a public disclosure requirement that might modify the lower court's on-sale caselaw in some unstated way, as shown by the panel's repeated emphasis on the content of public press releases, MGI's 8-K, and previously available public information. Cert. Pet. App. 38a-39a. The panel's holding that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed" (Cert. Pet. App. 43a) indicates the same. Notably, *before the AIA*, public knowledge of the existence of a sale was not relevant to whether a commercial sale had prior art effect or not. *See, e.g., In Re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001).

While the lower court's reasoning thus suggests that under the AIA a completely undisclosed business transaction would not operate as patent-defeating prior art, this is not necessarily so. The Court of Appeals unhelpfully warns that even entirely secret commercial sales may have prior art effect under its caselaw in the future, just as would have been the case before the AIA. Cert. Pet. App. 35a fn 7. Businesses, inventors, and the public are thus left at a loss.

Judge O'Malley's opinion concurring from denial of *en banc* rehearing does little to clarify the uncertainty caused by the panel's hedging. Judge O'Malley writes:

> [We did] not suggest that publicly announced agreements will always trigger the on-sale bar, nor [did we] suggest that secret sales never will. As we explained in *Medicines*, the confidential

> nature of a transaction is just one of several factors for determining whether the transaction rises to the level of a commercial sale such that the on-sale bar would apply.

Cert. Pet. App. 4a-5a. Judge O'Malley's statement, while correct, distracts from the main issue of this case. The real question is not how to determine when a transaction rises to the level of a commercial sale. The critical question is how to determine when a commercial sale rises to the level of prior art. This, the Federal Circuit declined to answer.

(b) The Court of Appeals' Concerns Over Abrogation of its On-Sale Jurisprudence are Overstated.

The change in the Federal Circuit's on-sale jurisprudence that would be caused by petitioner's interpretation of 35 USC § 102(a) is unlikely to be as fundamental or sweeping as the lower court believes. The Federal Circuit has developed comprehensive guidance on whether a transaction qualifies as a commercial sale or offer for sale, often involving fact-intensive questions of offer, acceptance, and contract formation; of delivery and payment terms; and whether the object of such a sale was sufficiently developed to qualify as a complete invention, ready for patenting. This body of caselaw continues to be applicable because the new section 102(a) still requires courts to engage in all the same inquiries: a transaction will still need to qualify as a commercial sale, the date of the sale will still need to be determined, and the invention will still need to be found ready for patenting. Only once these elements are established would courts additionally ask: "and did this commercial sale make the invention available to the public?"

Thus, the meaning courts have given to the words "on sale" for over a century remains undisturbed by the AIA. Likewise, nothing in the AIA abrogates this Court's seminal guidance in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), establishing the two principal conditions that an invention be the subject of a commercial offer for sale, and that it need not be reduced to practice so long as it is ready for patenting. Properly viewed, the 2011 amendments to 35 U.S.C. § 102 merely add a third condition, public availability, without displacing the other two.

(c) Judge O'Malley's Proposed Statutory Construction Has No Bearing on the Scope of "On-Sale" Prior Art After the AIA.

The only textual analysis of the 2011 amendments to 35 U.S.C. § 102 in the court below is found in Judge O'Malley's concurrence from denial of *en banc* rehearing,[7] in which Judge O'Malley explains that the words "otherwise available to the public" in section 102(a)(1) do not modify the preceding clauses.[8] Cert. Pet. App. 9a. For support, Judge O'Malley points to the provisions at 102(b)(1)(B), which juxtapose the terms "disclosure" and

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7. No trace of Judge O'Malley's analysis was contained in the precedential panel opinion, and it is unknown whether the other panel members share her reasoning.

8. If that were the case, the "public use" requirement would be equally unmodified, thus laying the foundation for preserving the patent-defeating effect not just of secret sales, but also of non-disclosing "public uses" that do not make the invention available or known to the public, such as in *Egbert v. Lippman*, 104 U.S. 333 (1881).

"publicly disclosed," thereby suggesting that not all prior art disclosures are necessarily "public." *Id.* 10a-11a.

This interpretation reads too much into section 102(b)(1)(B). The relevant section provides:

> (b) Exceptions.—
>
> (1) [...] A disclosure made 1 year or less before the effective filing date of a claimed invention **shall not be prior art to the claimed invention under subsection (a)(1)** if— [...]
>
> (B) the subject matter disclosed had, **before such disclosure, been publicly disclosed** by the inventor [...].

(Emphasis added).

Congress amended section 102(b) to specify what kind of event would not constitute patent-defeating prior art if it occurred within one year before the invention's effective filing date, referred to as the "grace period." Section 102(b)(1)(B) does not answer one way or another whether prior art under the AIA must be publicly available or not. Instead, a reading of subsections 102(a)(1) and (b)(1) together reasonably stands only for the simple proposition that all prior art events are disclosures, but not all disclosures are prior art.

Section 102(b)(1) specifies that not all third-party "disclosures" matter for purposes of the grace period – disclosures of the invention are relevant only if they would constitute an instance of patenting, printed publication, public use, on sale, or otherwise being made available to the public (i.e. "prior art ... under subsection (a)(1)").

Indeed, Congress's use of different words, "disclosure" and "prior art," suggests that the two are not coextensive.[9] Thus, other disclosures that do not constitute "prior art ... under subsection (a)(1)" would be irrelevant. An example would be the mere sharing of the details of an invention between business partners who are under an obligation of confidentiality.

Section 102(b)(1)(B) then permits the patent applicant to disqualify those disclosures that would constitute prior art under subsection (a)(1) and that were made one year or less before the effective filing date. In order to do so, the applicant must have antedated the disclosure with her own earlier disclosure. But again, not any applicant disclosure will work – only one that was made "publicly" will suffice.

By adding the word "publicly," Congress ensured that the applicant's antedating disclosure would *itself* have prior art effect, as it must. This is because section 102(b)(1)(B) does not limit when the applicant's public disclosure must have been made relative to the claimed invention's effective filing date. Thus, by its plain terms, section 102(b)(1)(B) allows a patent applicant to rely on her own public disclosures dating to *more* than 1 year before

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9. *See also* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy)("Indeed. . . subsection 102(b)(1)(A), as written, was deliberately couched in broader terms than subsection 102(a)(1). This means that any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being available to the public, is wholly disregarded as prior art."); (statement of Senator Hatch)("Indeed, a disclosure that does not satisfy the requirements to be prior art under section 102(a), nonetheless constitutes a disclosure that is fully protected under the more inclusive language of section 102(b).").

the effective filing date. For example, an applicant could properly disqualify a printed publication of the claimed invention made one year or less before the effective filing date with a public disclosure made five years before the effective filing date. The addition of the word "publicly" was thus necessary to avoid untenable results: absent a strict requirement for "public" disclosure, an applicant could secretly disclose her invention in ways that do not constitute prior art, wait indefinitely until someone else discloses the invention in a form that *does* constitute prior art, and then wait another whole year before filing a patent application.

Thus, Congress's choice of the terms "disclosure" and "publicly disclosed" in 102(b)(1)(B) can more simply and reasonably be explained as an effort to ensure that the AIA's grace period and prior art provisions work together harmoniously without producing aberrant results.

II. The Federal Circuit's Holding Is Inconsistent with the Government's Statutory Interpretation, Casting Doubt on Thousands of Patents.

(a) Patents Examined and Issued by the USPTO After the AIA May be Susceptible to Validity Challenges Based on Secret Prior Art.

The USPTO has interpreted post-AIA section 102(a) consistent with Helsinn and numerous *amici*, including BIO. Accordingly, for AIA patent applications, the USPTO has instructed its examiners to disregard secret sale activity as prior art. *United States Patent Office Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith*

America Invents Act, 78 Fed. Reg. 11,059,11,062; *see also* United States Patent Office Manual of Patent Examining Procedure § 2152.02(d) (9th ed. 2015). The USPTO started examining patent applications under the new prior art provisions on March 16, 2013. It is estimated that more than 300,000 patents have been examined and granted under the AIA's first-inventor to file provisions.

Clarification as to the proper statutory construction by this Court is urgent for these patentees who must consider the potential infirmities of patents issued under the USPTO's interpretation. Patents must continue to be examined, and patentees must continue to invest and build businesses in reliance on such patents. Meanwhile, available steps to potentially cure issued patents of problems arising from these divergent understandings of current section 102(a), such as reissue, 35 U.S.C. § 251, and supplemental examination, 35 U.S.C. § 257, are of little help. There are downsides to using these procedures: time and expense would be required to educate a new examiner on the claimed invention, and the patent may never successfully reemerge from reissue or supplemental examination. Reissue, for example, will only be granted if the patentee concedes an "error" that may have rendered the patent "inoperative or invalid." 35 U.S.C. § 251(a). No patentee would undertake such steps lightly. Thus, a reasonable business would be ill-advised to incur expense and risk without certainty as to what the new section 102(a) in fact means.

(b) Guidance is Needed So that Innovators Can Pursue Patenting, Commercial Transactions, and Business Activities Without Fear of Inadvertently Losing Their Rights.

Clarification is also necessary for inventors currently prosecuting patent applications and businesses structuring their transactions. While the USPTO's examination guidelines are consistent with the statutory text, the Federal Circuit's decision has cast them into doubt, leading to potentially inadequate patent examination that fails to protect inventors and the public. The Federal Circuit's ambiguity about the existence of a public availability requirement leaves many unanswered questions. For example, one or more arms' length transactions may precede the introduction of a product in the market. Sometimes such transactions are kept entirely secret – which, as the Federal Circuit unhelpfully cautions, may or may not save them from becoming prior art. More often, these transactions are referred to one way or another in the public sphere, for example by press release or SEC filing. Without knowing how to judge whether these references constitute prior art under section 102(a), businesses will not know how to govern reporting of their business activities, and patent applicants will not know what information to report to the USPTO during patent prosecution.

This issue is further complicated when one considers the effect of the Federal Circuit's holding on other portions of the section 102(a). The panel concluded that Congress' addition of "or otherwise available to the public" did not mean that prior art had to reveal an invention to the public to be invalidating. If the "public availability" clause

of section 102(a) indeed does not modify the preceding clauses, this would necessarily mean that "public use" references also do not need to make an invention available to the public to be prior art. If this is the case, businesses need to know. Transactions and public mentions of commercial activity are difficult to structure under the current state of the on-sale bar, but it is even more difficult to adjust the manner in which one "uses" an invention internally in one's business to avoid the pitfalls of the panel opinion. Thus, innovators who are using processes or products in secret may need to immediately file for patent protection, if still available.

(c) The Legislative History Supports the USPTO's Statutory Interpretation.

The arguments for or against the USPTO's interpretation of section 102(a) need not be repeated here, nor is it necessary to reprise the AIA's legislative history. But it would be fair to state that the USPTO's interpretation is supported by the legislative history, whereas the Federal Circuit's conclusion is not. Congress clearly removed all territorial restrictions on prior art from section 102(a), meaning that prior art references arising anywhere in the world can invalidate patents. Only two rationales are relevant to the "otherwise available to the public" inquiry: (i) Congress meant to make prior art global, but publicly accessible, or (ii) Congress meant to preserve secret prior art, but make it global. The legislative history includes support for only one interpretation. This is not an instance of competing legislator narratives and contradictory Congressional statements. Both the House and Senate Reports, for example, state plainly that Congress intended prior art under section 102(a) to

be art that is "available to the public." *See* H.R. Rep. No. 112-98, at 42, 43 (2011); S. Rep. No. 110-259, at 9, 32 (2008).

III. The Lower Court's Decision May Have Extraordinary Extraterritorial Implications That Were Likely Unintended by Congress.

Patent law is territorial. Prior to the AIA, the types of prior art embodied in 35 U.S.C. § 102(a) and 35 U.S.C. § 102(b) could be grouped into two categories: (1) patents and printed publications, and (2) knowledge, use, and on-sale activities. Category (1) prior art could exist "in this or a foreign country" whereas category (2) prior art was explicitly limited to those activities occurring "in this country." Foreign sales, use, and knowledge did not qualify. Thus, for over 100 years the policy of the on-sale bar was concerned with the domestic market and the interests of the American public. In harmonizing United States patent law with international practices through the AIA, Congress removed territorial restrictions on category (2) prior art.

The Federal Circuit's decision raises important questions about the effect of purely foreign conduct on the patentability of inventions made in this country. By including within the ambit of 102(a)'s on-sale bar commercial activity that does not convey an invention to the public, the Court of Appeals' decision for the first time extends a patent-defeating effect to foreign conduct having no nexus with, and being undetectable from, the United States.

No public policy is served by this result, indicating that it was not intended by Congress. The rationale

underpinning the pre-AIA on-sale bar was to prevent products long on sale in this country from being later withdrawn from the public by delinquent patenting. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-49 (1989). Similarly, courts were concerned that secret commercialization would permit an inventor to exploit his invention for an extended period of time before filing for patent protection, effectively extending his period of exclusivity to the detriment of the public. *See, e.g., Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829). But secret foreign sales do not implicate either of these concerns. For example, a non-public transaction between Japanese and Korean companies in Seoul, without more, does not impact what goods are available to American consumers, nor does it have any relevance to an unknowing domestic inventor's likelihood of obtaining patent protection.

Indeed, the Federal Circuit's ruling is in tension with United States patent law's focus on how a patentee orders his affairs, not the unknowable activities of third parties. This Court and the Federal Circuit have focused on the concern that the patent applicant will delay his patent filing in order to commercially profit from his invention beyond the statutory term. Cert. Pet. App. 13a (collecting cases). As expressed in *Pfaff*, the patent laws seek to protect "the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65 (emphasis added). And even in other contexts, such as patent exhaustion, this Court has explained that it is the patentee's own decisions that determine when his rights will be extinguished. *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1537 (2017). To be sure, foreign activities that make inventions available to the public

are relevant to United States patent law in an age of the internet, borderless social media, and international online retail sales. But there is no explanation of why our patent laws would suddenly focus on secret foreign activities that inherently cannot affect U.S. inventors and the American public.

In turn, foreign inventors are just as likely to be unjustly impacted. Prior to the AIA, sales (public and non-public) in foreign countries had no impact on an inventor's ability to obtain patent protection in the United States. Now, under the Federal Circuit's ruling, non-public transactions that may not be patent-defeating and do not even constitute a "sale" in a foreign country can be patent-defeating in the United States. For example, the Federal Circuit looks to the Uniform Commercial Code (U.C.C.) to determine whether a transaction constitutes a commercial sale or offer for sale under section 102(a). *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc). But many countries do not have an equivalent to the U.C.C. We know from the Convention on Contracts for the International Sale of Goods that a number of countries permit oral contracts for the sale of goods, whereas the U.C.C. does not, and many countries do not follow the "battle of the forms" approach embodied in the U.C.C. *See* T. McNamara, *U.N. Sale of Goods Convention: Finally Coming of Age?*, 32-Feb. Colo. Law 11 (2011). Thus, in essence, the Federal Circuit's opinion reaches into foreign domains to control the activities of foreign inventors. But there is no policy support for regulating such foreign, non-public conduct.

IV. The Negative Policy Ramifications of the Federal Circuit Decision are Contrary to the Purposes of the AIA and Make Meaningless Explicit Protections that Congress Wrote Into the Statute.

No productive policy is served by permitting the lower court decision to stand. To the contrary, the decision stands in tension with Congress' stated policy goals, including fostering harmonization with international practice[10] and creating more predictability for businesses and the public. It also operates inconsistent with the long-standing principles underlying the "on-sale bar," namely this Court's concern that patenting inventions previously on sale will remove existing knowledge from the public. *Pfaff*, 525 U.S. at 64; *Bonito Boats*, 489 U.S. at 141. Instead, the knowledge of the invention disclosed prior to filing the patent applications is not equivalent to what was "removed from public use" by an issued patent.

Rather, the Federal Circuit set up a scenario wherein by preserving a particularly problematic category of secret prior art in the amended 35 U.S.C. § 102, patents are denied to deserving, and innocent inventors who could

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10. The patent laws of significant United States trading partners do not bar patents on the basis of secret sales. For example, under European Patent Office law there is no bar for patenting after a confidential disclosure related to commercial use, e.g. a sales agreement. E.g., *Union Carbide Corp. v. Linde A.G.* [1991] T024188 [E.P.O.] Japan has a sale bar, but if the invention is offered for sale in secret, or under a duty of confidentiality, novelty is preserved. Article 29 Japan Patent Office ("JPO"). One skilled in the relevant art must be able to understand the invention as a result of the public sale. JPO Examination Guidelines Part II. Chapter 2. Section 1.5.3(3)(II).

not have known of invalidating business transactions. This is because the amended prior art provisions at 35 U.S.C. § 102(a) treat all patent applicants the same, regardless of who created such prior art. Thus, if a prior "secret sale" constitutes prior art, it does so against any patent applicant – not just against applicants that were parties to the sale, but also against applicants who independently invented, diligently disclosed their invention in a patent application, and who could not have known of that sale at all. This unfairness is compounded by expanding the scope of such secret prior art to the rest of the world. There is no competing policy support for the regime created by the Federal Circuit's system; only inscrutable complications for innovative business.

To the extent that the Federal Circuit based its decision on a policy-based concern that removing secret sales from the scope of section 102(a) prior art would incentivize such transactions to the detriment of the public, that concern is ameliorated by the fact that Congress plainly condoned such activity in the AIA itself. In 35 U.S.C. § 273, Congress explicitly provided protections for inventors who secretly commercialize their inventions for profit and competitive advantage, without creating prior art, and without defeating the patentability of later-filed patent applications.

In 35 U.S.C. § 273, the AIA established a comprehensive set of "prior commercial user" rights under which a commercial user can engage in a for-profit exploitation of an invention for more than one year before the filing date of another's patent application. A typical scenario would be a business that uses an inventive machine to more efficiently manufacture articles for sale, thus gaining a

competitive advantage over competitors, or a company that sells services to customers using its own inventive software. If the invention is later independently patented by another, and that patentee then sues the prior user for such longstanding, ongoing commercial use, the prior user has a personal defense against claims of infringement.

To establish this defense, the exploitation of the later-patented invention must precede the filing of the later patent application by more than one year and must be "commercial" and "internal." Importantly, such exploitation by the first user does not invalidate the inventor's later filed patent. 35 U.S.C. § 273(g).

Thus, Congress recognized that even significant commercial, for-profit exploitation of an invention, including the sale of manufacturing services and other benefits, does not constitute prior art, so long as it does not disclose the invention to the public. If such exploitation were prior art, there could not be a later patent, and the new defense codified at 35 U.S.C. § 273 would have been unnecessary.

CONCLUSION

The negative policy implications arising from the Federal Circuit's decision cannot be mitigated without intervention by the Court. For these reasons, BIO respectfully requests that the Petition for a Writ of Certiorari be granted.

Respectfully submitted,

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